REMARKS

Claims 1, 4-20, 32-44, and 48-52 remain pending in the application. Claims 13-20 and 33-40 were previously withdrawn. Claims 2, 3, 21-31, and 45-47 are hereby canceled without prejudice or waiver of the right to pursue the subject matter of said claims in this or another application. Claims 1, 4, 6, 8, 10, 12, 32, 41-44, and 48 have been amended. All other claims remain unchanged. Reconsideration of the pending claims is respectfully requested.

Claims 1, 12, 32, 41, and 42 were amended to correct an antecedent basis issue so that all of the claims refer to a "drug-containing water soluble and/or erodible external coat". Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the original specification (pg. 3, ln. 12, 25-27; pg. 4, ln. 2-19; pg. 5, ln. 10; pg. 11, ln 2-15; pg. 26, ln. 7-16; Examples 2 and 4) and claims (41-42).

Claim 1 was also amended to add the subject matter of claim 3.

Claims 4, 6, 8, 10, 12, 32, 41-44, and 48 were amended to correct the dependencies thereof in order to reconcile the claims following cancelation of parent claims.

Claims 1-12, 21-32 and 42-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. (U.S. 4,783,337) and Faour (U.S. 6,352,721) in view of Savastano et al. (U.S. 5,681,584) and Christgau et al. (WO 2005/123130). Examiner relies upon the '337 Patent as disclosing an osmotic with two drug-containing compositions in the core surrounded by a membrane, wherein the core can release drug according to a "broad range of drug delivery rates". The '721 Patent is relied upon as disclosing a dual controlled release/osmotic pumping drug delivery device having a core made from a centrally located expandable nucleus surrounded by a drug-containing composition for releasing drug according to "in a controlled, continuous and approximately steady, preferably zero order, rate over a prolonged period of time." Examiner acknowledges that the '337 and '721 Patents do not suggest use of licofelone in the osmotic device. Examiner then relies upon the '584 Patent as disclosing an enteric coated osmotic device having a delay jacket between the semipermeable membrane and the drug-containing core. Examiner then fails to provide any basis upon which the '130 Publication is relied upon and finally relies upon the disclosure of "Smolka et al." (PCT International Publication No. WO 03/097041) as disclosing controlled or extended release dosage forms containing licofelone (ML3000) and the desired

pharmacokinetic parameters for such dosage forms. Insofar as it may apply to the present claims, this rejection is traversed.

Applicants respectfully submit that Examiner has made an improper rejection of the claims. The rejection, as set forth in the office action (pg. 3, section 3), does not indicate reliance upon the '041 PCT Publication as a basis for rejection and instead indicates reliance upon the '130 PCT Publication as a basis for the rejection. However, in Examiner's arguments following the rejection, Examiner fails to rely upon the '130 PCT Publication and then improperly relies upon the '041 Publication. Applicants believe that the rejection as set forth in the office action is formally improper, and the claims as pending are patentable over the references of record. Nonetheless, Applicants have addressed the rejection as if it were a proper rejection and based upon prophetic combination of the '337 Patent, '721 Patent, '584 Patent and '041 PCT Publication in order to advance prosecution of the application.

Applicants respectfully submit that Examiner's rejection of the claims is based upon impermissible hindsight reconstruction, which still fails to arrive at the invention as claimed.

Applicants acknowledge that the '337 Patent and the '721 Patent disclose different types of osmotic devices for use in release drugs according to different release profiles and that neither of the two patents suggest inclusion of licofelone in an osmotic device. Applicants also acknowledge that the '584 Patent discloses an enterically coated osmotic device having a delay jacket between a drug-containing core and a semipermeable membrane. Applicants also acknowledge that the '041 PCT Publication generally suggests that licofelone in combination with a proton pump inhibitor can be included in an extended release or controlled release dosage form. However, the instant claims are not merely directed to a broadly defined osmotic device comprising licofelone in the core.

The instant claims specify an osmotic device comprising a drug-containing core surrounded by a semipermeable membrane having at least one preformed passageway which is then surrounded by a drug-containing water soluble and/or erodible external coat, wherein the drug in the core and external coat is licofelone, and the licofelone is released from the core according to a specified release profile. The charge of licofelone in the coating serves as a loading dose to rapidly increase a subject's licofelone plasma concentration and rapidly provide a therapeutic benefit. The charge of licofelone in the core serves to maintain the plasma concentration in the subject above a minimum therapeutic threshold for an extended period of time. The specific release profile provides a certain amount of licofelone released during a specified period of time after administration such that the

intended therapeutic threshold can be achieved. The specific release profile provides a balance between the rate of plasma clearance of licofelone, its rate of absorption by a subject following release from the osmotic device, and the rate of initiation and maintenance of the desired therapeutic benefit to be achieved in the subject.

Applicants submit that the prophetic combination of art of record fails to provide motivation to prepare an osmotic device as defined in the instant claims including all of the limitations therein. The art of record fails to suggest that there would be any advantage to preparing one type of extended release dosage form over another or one type of controlled release dosage form over another. It also fails to provide any motivation to prepare an osmotic device as claimed which is capable of providing the specified release profile over another release profile, such as those defined in the canceled claims. Applicants note that the release profile of the osmotic device is associated with the licofelone plasma concentration profile provided by the osmotic device, and the plasma concentration profile is ultimately associated with a target therapeutic benefit to be provided to a subject. It is Applicant's belief that the claimed release profile results in a therapeutic benefit different than what would be achieved by another device having a different release profile. Without any motivation to provide an osmotic device having the specifically claimed release profile, the prophetic combination of references fails to obviate the invention as claimed.

Examiner argues that it is obvious to make "the drug available instantly to a drug receptor by substantially eliminating the start-up drug delivery time frequently required to deliver some drugs by osmotic device for performing its beneficial effects." However, Examiner overlooks the fact that the plasma concentration of a drug is often correlated with the occurrence and/or severity of side effects caused by the drug. If the loading dose of a drug is too high, the occurrence and/or severity of side effects may or may not be high depending on the toxicology profile of the drug. Examiner's open statements infers that there would be no difference in the observed side effects caused by licofelone regardless of the amount of the loading dose and there would therefore be no motivation to provide a certain percentage of the total dose in a device as a loading versus as a plasma concentration maintenance dose. Such an assumption finds no support in the art of record and appears to be based merely upon Examiner's conjecture. For example, claims 12 and 32 specify, "the drug-containing water soluble and/or erodible external coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device." Applicant fails to see where the art of record provides any motivation to prepare such a device. To the point, the only

relevant art of record concerning an extended or controlled release dosage form of licofelone is the '041 PCT Publication. However, the '041 PCT Publication merely provides a desired minimum target plasma concentration of licofelone without any suggestion or teaching as to how a respective extended release or controlled release dosage form would need to be constructed in order to achieve such a result. In other words, the '041 PCT Publication merely provides a problem to be solved without providing any solution thereof.

In summary, the prophetic combination of references fails to provide the necessary motivation to prepare an osmotic device having the specified release profile as now claimed.

Accordingly, Applicants submit that the rejection of claims 1-12, 21-32 and 42-52 under 35 U.S.C. §103(a) has been over come and request that it be withdrawn. Reconsideration of the claims as now pending is requested.

Applicants have made a diligent effort to advance the prosecution of the application by amending the claims and presenting arguments in support of patentability. In view of the above, Applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

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